DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 7, 2015

Philips Medical Systems Nederland B.V.
% Ms. Susan Quick
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland) Inc.
595 Miner Road
CLEVELAND OH 44143

Re: K150665
Trade/Device Name: Philips Spectral CT Applications
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, LLZ
Dated: July 28, 2015
Received: July 29, 2015

Dear Ms. Quick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150665

Device Name

Philips Spectral CT Applications

Indications for Use *(Describe)*

The Philips Spectral CT Applications support viewing and analysis of images at energies selected from the available spectrum in order to provide information about the chemical composition of the body materials and/or contrast agents. The Spectral CT Applications provide for the quantification and graphical display of attenuation, material density, and effective atomic number. This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of anatomical and pathological structures.

The Spectral enhanced Advanced Vessel Analysis (sAVA) application is intended to assist clinicians in viewing and evaluating CT images, for the inspection of contrast-enhanced vessels.

The Spectral enhanced Comprehensive Cardiac Analysis (sCCA) application is intended to assist clinicians in viewing and evaluating cardiovascular CT images.

The Spectral enhanced Tumor Tracking (sTT) application is intended to assist clinicians in viewing and evaluating CT images, for the inspection of tumors."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary
[As required by 21 CFR 807.92(c)]

Applicant's Name:	Philips Medical Systems Nederland B.V.
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510(k) Summary Date of Preparation:	05-March-2015
Device Trade Name:	Spectral CT Applications
Common or Usual Name:	Computed Tomography X-ray System (CT System)
Classification	
Name:	Computed Tomography X-ray System
Regulation:	21 CFR 892.1750
Class:	II
Product Code:	JAK, LLZ
Panel:	Radiology
Predicate devices	IQon Spectral CT (K133674) EBW NM 2.0 (K111336) Brilliance iCT (K060937)

Device Description: The Spectral CT Applications package introduces a set of three SW clinical applications: spectral enhanced Comprehensive Cardiac Analysis (sCCA), spectral enhanced Advanced Vessel Analysis (sAVA), and spectral enhanced Tumor Tracking (sTT). Each application provides tools that assist a trained personal in visualization and analysis of anatomical and pathological structures.

The sCCA application is targeted to assist the user in analysis and diagnostic of Cardiac Cases, as contrast enhanced and ECG triggered scans. The application input is a cardiac case that was acquired on the IQon CT scanner; the application takes the user through typical workflow steps that allow him to extract qualitative and quantitative information on the coronary tree and chambers. The output of this application is information on physical (length, width, volume) and composition properties (Effective Atomic number, Attenuation, HU) of the coronary vessel & findings along it.

The sAVA application is targeted to assist the user in analysis and diagnostic of CT Angiography cases, as contrast enhanced and whole body CT-angiography scans. The application input is a CT Angiography case that was acquired on the IQon CT scanner; the application takes the user through typical workflow steps that allow him to extract qualitative and quantitative information on the vessel of interest. The output of this application is information on physical (length, width, volume) and composition properties (Effective Atomic number, Attenuation, HU) of the vessels & findings along it.

The sTT application is targeted to assist the user in analysis of tumors, as contrast enhanced, soft tissue oriented, and whole body scans. The application input is a tumor suspected contrast enhanced case that was acquired on the IQon CT scanner; the application takes the user through typical workflow steps that allow him to extract qualitative and quantitative information on the tumor of interest. The output of this application is information on physical (length, width, volume) and composition properties (Effective Atomic number, Attenuation, HU) of the tumor.

Intended Use:

The Philips Spectral CT Applications support viewing and analysis of images at energies selected from the available spectrum in order to provide information about the chemical composition of the body materials and/or contrast agents. The Spectral CT Applications provide for the quantification and graphical display of attenuation, material density, and effective atomic number. This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of anatomical and pathological structures.

The Spectral enhanced Advanced Vessel Analysis (sAVA) application is intended to assist clinicians in viewing and evaluating CT images, for the inspection of contrast-enhanced vessels.

The Spectral enhanced Comprehensive Cardiac Analysis (sCCA) application is intended to assist clinicians in viewing and evaluating cardiovascular CT images.

The Spectral enhanced Tumor Tracking (sTT) application is intended to assist clinicians in viewing and evaluating CT images, for the inspection of tumors.

Substantial Equivalence:

Philips has identified one Primary and two Reference predicate devices for the Spectral CT Applications.

The Primary predicate, Spectral CT viewer (part of Philips IQon Spectral CT), addresses the enhanced visualization and analysis capabilities of spectral images derived by the spectral data.
The Reference predicates address functionality of the baseline applications AVA, CCA, and TT.

Table 5-1 Primary Predicate

Device trade name	510(k) number	Product code
Philips IQon Spectral CT (Spectral CT Viewer)	K133674	JAK

Table 5-2 Reference Predicates

Spectral CT Applications	Reference Predicate	510(k) number	Product code
sAVA	AVA from Brilliance iCT (Brilliance Volume)	K060937	JAK
sCCA	CCA from Brilliance iCT (Brilliance Volume)	K060937	JAK
sTT	TT from EBW NM 2.0	K111336	LLZ

Intended Use and Indications for Use Discussion
The proposed intended uses of the Spectral CT Applications are combining indications coming from their primary and reference predicates.
Similar to the reference predicates (CCA, AVA: K133674, K060937; TT: K111336**)**, the Spectral CT Applications assist clinicians in viewing and evaluating CT images of Cardiac, Angiography, and Tumor related cases. The differences between the intended use of the Reference predicates and the proposed Spectral CT applications is that the Spectral CT applications introduce capabilities of viewing and analysis of CT images of Cardiac, Angiography, and Tumor related cases at energies selected from the available spectrum in order to provide information about the chemical composition of the body materials and/or contrast agents. The Spectral CT Applications provide for the quantification and graphical display of attenuation, material density, and effective atomic number which is not available with the reference predicates.

Technological Characteristics

The proposed Spectral CT Applications (sAVA, sCCA, and sTT) are based on Spectral CT Viewer (K133674) as the Primary predicate, while incorporating basic tools, like: measurements, Display modes (2D, 3D) and layouts, etc. and enhanced visualization and analysis capabilities that are derived from utilization of spectral data.
These enhanced visualization and analysis capabilities include spectral plots, keV slider, and Spectral Magic Glass.

The proposed Spectral CT Applications (sAVA, sCCA, and sTT) are based on the baseline applications mentioned above as the reference predicates while sharing the characteristics of those baseline applications, mainly:

- Both AVA and sAVA support whole body CT Angiography (CTA) scans and assist clinicians in viewing and evaluating CT images, for the inspection of contrast-enhanced vessels.
- Both CCA and sCCA support cardiac CT scans and assist clinicians in viewing and evaluating cardiovascular CT images.
- Both TT and sTT support whole body CT scans and assist clinicians in viewing and evaluating CT images, for the inspection of tumors.
- The Spectral CT Applications (sAVA, sCCA, and sTT) incorporate – in the high level - the same workflow stages and functionalities as the reference predicate baseline CT Applications; and in more details, allow to generate presets and layouts and provide measurement tools, segmentation tools, and summary tables similar to the reference predicate baseline CT Applications.

The difference between the Primary predicate and the Spectral CT applications is the customized workflow and summary tables that are tailored to meet the specific case of interest.
The differences between the Spectral CT applications and the baseline CT Application reference predicates is in the enhanced visualization and analysis capabilities that are derived from utilization of spectral data.

Table 5-3: Main functionalities and characteristics of Predicates vs. Spectral CT Applications

Features	Proposed Spectral CT Applications	Primary Predicate (K133674)	Reference Predicate (K060937, and K111336)
SW Clinical application	Yes	Yes	Yes
Incorporate workflow stages	Yes	Yes	Yes
Supports conventional images	Yes	Yes	Yes
Supports spectral images, including: SBI, Material Density Pairs, MonoE	Yes	Yes	No
DICOM compliant	Yes	Yes	Yes
Supports Axial (2D) and volumetric (3D) visualization modes	Yes	Yes	Yes
Provides presets and layouts for conventional images	Yes	Yes	Yes
Provides presets and layout for spectral images	Yes	Yes	No
Provides measurement tools: average, STD, length, area, volume, and spectral plots	Yes	Yes	Yes
Provides measurement tools: spectral plots	Yes	Yes	No
Provides segmentation tools: clipping, inject, delete	Yes	Yes	Yes
Provides segmentation tools: bone/skull removal, couch removal	Yes – in Spectral Enhanced AVA application	No	Yes – in AVA application
Provides segmentation tools: coronary & chambers	Yes – in Spectral Enhanced CCA application	No	Yes – in CCA application
Provides summary tables	Yes	No	Yes
Generates “on-the fly” datasets	Yes	Yes	No
Provides keV slider	Yes	Yes	No
Provides spectral magic glass	Yes	Yes	No

The Spectral CT Applications are similar to the applications that are incorporated in the cleared predicate devices. The Spectral CT

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Summary of Non-Clinical Testing:	Spectral CT applications have been verified through SW verification process. In which covered Functionality, risk mitigations, and IFU. The Verification was using datasets that were generated by the Philips IQon Spectral CT system (K133674) and Verification testing specs to methodically cover functionality as described in the requirement specification documents. The verification indicated that SW requirements were met and IFU contains appropriate clarification on functionality and warnings. The conclusions are summarized in the Verification report.
Summary of Clinical Testing:	Spectral CT applications have been validated to show that intended uses of the spectral CT applications are met. Validation stage was using clinical datasets derived from Philips IQon Spectral CT system (K133674) and the SW version that successfully passed verification process. The intended uses of each application were evaluated by Philips Internal certified radiologists that represented a typical user. The evaluators were questioned against each of the intended uses and provided score to describe their level of satisfaction. The validation indicated that intended uses and defined user needs were met, hence: sCCA and sAVA applications allow visualization, manipulation and analysis of spectral data and that sTT application assist clinicians in viewing and evaluating CT images for the inspection of tumors.
Conclusion:	Philips Medical Systems believes that the Spectral CT Applications are similar to the applications that are incorporated in the predicate devices. There are no significant differences that may raise new issues of safety or effectiveness. Bench tests have been performed to demonstrate that the Spectral CT Applications are as safe and effective as the applications that are incorporated in the predicate devices, without raising any new safety and/or effectiveness concerns.